UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,041	05/23/2005	Ercem Atillasoy	PD/4-32564A/USN	7041

1095 7590 02/28/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/519,041	ATILLASOY ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 4-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 4-6 is/are rejected.

7)☒ Claim(s) 6 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12/22/04, 5/23/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of Application number 10/519,041 filed on 05/23/2005. Claims 1-3 have been cancelled and claims 4-6 have been added in a preliminary amendment filed on 12/22/2004. Accordingly, claims 4-6 are presented for examination on the merits.

Information Disclosure Statement

The information disclosure statement filed 12/22/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The Examiner has drawn a line through the references.

Claim Objections

Claim 6 is objected to because of the following informalities: Claim 6 recites a pack containing pharmaceutical compositions according to claim 2... Claim 2 has been cancelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villars et al. (British Journal of Dermatology 1992, 126, supplement 39, 61-69).

Villars et al. teach the treatment of 4 patients with 500 mg/day of terbinafine for sinusitis noting nasal passage obstruction and cerebral involvement, which the Examiner interprets to mean rhinosinusitis (Page 66, Table 2). Since rhinitis means inflammation of the nasal passages and sinusitis means inflammation of the sinuses and rhinosinusitis means inflammation in both areas and rhinitis is more appropriately termed rhinosinusitis (Page 1 of 7, reference W). Villars et al. teach that patients receiving 500 mg/day terbinafine did not report more side effects than patients receiving oral terbanifine 250 mg/day (Page 67, Table 4 and the section on tolerability). Villars et al. teach that a recurrence rate of 18% was recorded for patients using terbinafine (Page 65, upper left column).

Villars et al. do not expressly teach a method for the treatment of chronic rhinosinusitis comprising administering to a patient in need thereof about 625 mg or about 725 mg terbinafine in free or acid addition salt form or a pharmaceutical composition comprising about 625 mg or about 725 mg terbinafine in free or acid addition salt form in oral dosage form.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to increase the dosage of terbinafine in a pharmaceutical composition for the treatment of chronic rhinosinusitis of Villars et al. for the purpose of decreasing the relapse/reinfection rate and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because higher doses of terbinafine are well tolerated as taught by Villars et al. and an increase in drug concentration might decrease the reinfection rate and lead to a better quality of life for the patient.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been suggested by the teaching of the cited reference.

Claim Rejections - 35 USC § 103

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ponikau (WO 99/20261).

Ponikau teaches a method of treating a mammal having a non-invasive fungus-induced rhinosinusitis, comprising mucoadministering to at least a portion of the nasal-paranasal anatomy of said mammal a formulation in an amount, at a frequency, and for

a duration effective to reduce or eliminate said non-invasive fungus-induced rhinosinusitis, said formulation comprising an antifungal agent (claim 1), wherein the non-invasive fungus-induced rhinosinusitis is chronic (claim 6) and the formulation is in a solid, liquid or aerosol form (claim 7), wherein the antifungal agent can be terbinafine hydrochloride (claim 17), wherein the formulation comprises a pharmaceutically acceptable aqueous vehicle and the formulation comprises about 0.01 ng to about 1000 mg of the antifungal agent per liter (claims 21 and 22). Ponikau teaches an article of manufacture, comprising packaging material and a formulation, which comprises an antifungal agent for the treatment of rhinosinusitis (claims 70, 71 and 78). Ponikau teaches an antifungal composition comprising an antifungal agent (terbinafine hydrochloride), a flavoring, and water (claim 110).

Ponikau does not expressly disclose the method or composition or pack comprising about 625 mg or about 725 mg terbinafine in free or acid addition salt form.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use about 625 mg or about 725 mg of terbinafine in free or acid addition salt form for: 1) a method for the treatment of chronic rhinosinusitis in a patient; 2) a pharmaceutical composition; and 3) a pack containing the pharmaceutical composition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Ponkau teach that a wide range of antifungal concentrations can be used in the invention (Page 6, lines 1-19) and one of ordinary skill in the art would either know the

appropriate dosage amount or be able to calculate the proper dosage amount based upon the patient.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been suggested by the teaching of the cited reference.

Claim Rejections - 35 USC § 103

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurlimann et al. (Dermatology 2001 202, 330-332).

Hurlimann et al. teach a method treatment of a patient suffering from rhinoconjunctivitis with oral therapy of terbinafine (250 mg/day) (Abstract). Rhinoconjunctivitis is a combination of rhinitis and conjunctivitis. Rhinitis is an inflammation of the nasal mucous membrane that lines the nose and sinus. For Applicant's benefit, the Examiner has attached a reference, which points out that sinusitis is an inflammatory process that involves one or more of the four paired paranasal sinuses and is more appropriately termed rhinosinusitis (Page 1 of 7, reference W). The Examiner interprets that the patients suffering from rhinoconjunctivitis also had rhinosinusitis.

Hurlimann et al. do not expressly disclose the method or composition comprising about 625 mg or about 725 mg terbinafine in free or acid addition salt form.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition and method of Hurlimann et al. by using about 625 mg or about 725 mg terbinafine in free or acid addition salt form and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Hurlimann et al. teach that the standard dose of terbinafine may be insufficient to completely eliminate some of the organisms resulting in relapse after discontinuation of treatment (Page 330, middle column; and page 331, right column last paragraph).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been suggested by the teaching of the cited reference.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA

Alton Pryor
Primary Examiner
A.U. 1616